UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, ex rel. DAVID KESTER, Plaintiffs and Relator, - against - NOVARTIS PHARMACEUTICALS CORPORATION, et al., Defendants.	11 Civ. 8196 (CM) (JCF) MEMORANDUM AND ORDER

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

The United States of America (the "Government") and 11 states (the "Litigating States")[1] each intervened as plaintiffs in this qui tam action, alleging, among other things, that defendant Novartis Pharmaceuticals Corporation ("Novartis") is liable under the False Claims Act, 31 U.S.C. §§ 3729-3733, because it violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and, as a result, was unjustly enriched. Novartis has filed a motion to compel production of documents from the Government and the Litigating States pursuant to Rule 37 of the Federal Rules of Civil

[1] The states are Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin, which filed their complaint as a group, and California and Washington, which each filed its own complaint.

Procedure. On the basis of the parties' papers and oral argument, the motion is granted in part and denied in part.

Background

A. Factual Allegations

In a number of prior opinions, including United States ex rel. Kester v. Novartis Pharmaceuticals Co., __ F. Supp. 2d __, __, 2014 WL 2324465, at *2-6 (S.D.N.Y. 2014) ("Novartis I"), and United States ex rel. Kester v. Novartis Pharmaceuticals Co., __ F. Supp. 2d __, __, 2014 WL 4230386, at *1-2 (S.D.N.Y. 2014) ("Novartis IV"), the Honorable Colleen McMahon, U.S.D.J., has explained the primary theory of liability that the Government and the Litigating States advance. In short, the False Claims Act imposes liability on any person who, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government, 31 U.S.C. § 3729(a)(1)(A); "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" to the federal government, 31 U.S.C. § 3729(a)(1)(B); or conspires to commit those violations, 31 U.S.C. § 3729(a)(1)(C). The Anti-Kickback Statute "forbids [knowingly and willfully] offering, paying, soliciting, or receiving 'remuneration' (i.e., kickbacks) in exchange for recommending drugs covered by Medicare and Medicaid." Novartis IV, __ F. Supp. 2d at __, 2014 WL 4230386, at *1; 42 U.S.C. § 1320a-7b(b)(1). Each of the Litigating States forbids similar conduct by statute, regulation, or other requirement. (State of California's First Amended Complaint-in-Intervention ("California Compl."), ¶ 20);

First Amended Complaint in Intervention of the States of Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin against Novartis Pharmaceuticals Corporation ("Multistate Compl."), ¶¶ 29-62; State of Washington Complaint in Intervention ("Washington Compl."), ¶¶ 19-24). The plaintiffs in this case allege that Novartis paid kickbacks in the form of cash rebates (or discounts) and patient referrals to certain specialty pharmacies in connection with two of its drugs: Exjade, a drug used to reduce iron overload in the blood of patients who receive blood tranfusions,[2] and Myfortic, an immunosuppressant that helps prevent organ rejection in transplant patients. See Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *2; Novartis IV, __ F. Supp. 2d __, 2014 WL 4230386, at *1.

The Government and the Litigating States allege that the Exjade scheme exploited Novartis' control over patient referrals through its "exclusive patient distribution network" for the drug, called EPASS. Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *3; (Novartis Pharmaceuticals Corporation's Memorandum of Law in Support of its Motion to Compel Further Discovery Responses from the United States and from the States of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington and Wisconsin ("Novartis Memo.") at 6). Under this plan, which was instituted after Novartis noticed a "'performance gap' between [its] sales targets and actual Exjade sales," the company conditioned the ability of BioScrip, a

[2] The process is called "iron chelation."

specialty pharmacy, to access EPASS and to earn rebates on BioScrip's "increasing the refill rates among its Exjade patients[] and [] convincing patients who had stopped ordering refills to resume doing so." Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *3. According to the Government, what Novartis calls "adherence initiatives" (Novartis Memo. at 2) consisted of poorly-trained BioScrip staff calling patients "to offer purported 'counseling' about Exjade therapy." Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *3. The Government asserts that this counseling was actually a strategem involving Novartis marketing personnel "designed to get patients to order refills" notwithstanding certain safety concerns.[3] Id.; (Memorandum of Law of the United States in Opposition to Novartis' Motion to Compel ("Government Memo.") at 6-7).

The Government (but not the Litigating States) contends that in the Myfortic gambit, Novartis offered rebates or discounts to certain pharmacies as a quid pro quo for "us[ing] their influence to recommend that doctors switch [] transplant patients from other medications[, particularly Myfortic's main competitor CellCept,] to Myfortic," and for dissuading physicians from recommending that patients switch from Myfortic to CellCept or its generic formulation. Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *2-3.

These violations of the Anti-Kickback Statute assertedly

[3] The Government settled its claims against BioScrip in January 2014. (Stipulation and Order of Settlement and Dismissal as to BioScrip, Inc. dated Jan. 8, 2014).

ripened into violations of the False Claims Act when the pharmacies repeatedly certified that they were in compliance with the Anti-Kickback Statute in their claims for reimbursement from government programs. Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *4-6; Novartis IV, __ F. Supp. 2d at __, 2014 WL 4230386, at *11-16; (California Compl., ¶¶ 117-120; Multistate Compl., ¶¶ 154-158; Washington Compl., ¶¶ 49-50).

B. Discovery Requests

There are two general categories of documents at issue here.[4] In the first, Novartis seeks from the Government documents related to its "own initiatives to promote medication adherence" -- that is, a patient's conformance with recommendations regarding medication -- specifically:

> Adherence-related components or requirements of certain federal health-related programs and grants, and other federal adherence-related policies, activities, programs, plans, or initiatives;[5]
>
> The [Government's] exclusion of communications encompassing adherence-related communications from the definition of "marketing" in certain laws and regulations and its publication regarding refill reminders;[6] and

[4] Documents responsive to a third requested category have been produced, mooting that portion of the motion. (Letter of Manisha M. Sheth dated September 26, 2014).

[5] These documents are solicited by Requests for Production ("RFP") Nos. 71-73, 80, 82, 89-90 and 92. (Novartis Pharmaceuticals Corporation's Fourth Set of Requests for Production of Documents ("Novartis Fourth RFP"), attached as Exh. I to Declaration of Manisha M. Sheth dated Sept. 10, 2014 ("First Sheth Decl."), Nos. 71-73, 80, 82; Novartis Pharmaceuticals Corporation's Sixth Set of Requests for Production of Documents ("Novartis Sixth RFP"), attached as Exh. J to First Sheth Decl., Nos. 89-90, 92).

[6] These documents are solicited by RFP Nos. 75-78. (Novartis Fourth RFP, Nos. 75-78).

> The [Government's] report regarding the budgetary impact of medication adherence and other documents regarding the savings, costs, and/or patient outcomes associated with medication adherence.[7]

(Novartis Memo. at 10 (internal citations omitted)). Novartis asks the Litigating States for similar documents.[8] (Novartis Memo. at 13). The second category consists of documents related to treatment protocols:

> Documents reflecting or relating to any treatment protocols for kidney transplants and iron chelation therapy performed at federally[-]operated healthcare facilities;[9]
>
> Documents relating to the administration of Exjade or the promotion of Exjade treatment adherence developed by certain federal agencies or provided by [healthcare providers] at [Veterans Affairs] facilities;[10] and
>
> The identities of "any [provider of healthcare services] at a [Veterans Affairs] hospital who makes prescribing decisions of appropriate medications for patients after kidney transplant surgery."[11]

---

[7] These documents are solicited by RFP Nos. 79, 81 and 91. (Novartis Fourth RFP, Nos. 79, 81; Novartis Sixth RFP, No. 91).

[8] These documents are solicited from the Litigating States by RFP Nos. 36, 38-39 and 50. (E.g., Novartis Pharmaceuticals Corporation's First Set of Requests for Production of Documents to California ("Novartis First RFP to California"), attached as Exh. K to First Sheth Decl., Nos. 36, 38-39); Novartis Pharmaceuticals Corporation's Second Set of Requests for Production of Documents to California ("Novartis Second RFP to California"), attached as Exh. V to First Sheth Decl., No. 50).

[9] These documents are solicited by RFP Nos. 19 and 99 (Novartis Pharmaceuticals Corporation's Second Set of Requests for Production of Documents ("Novartis Second RFP"), attached as Exh. KK to First Sheth Decl., No. 19); Novartis Sixth RFP, No. 99).

[10] These documents are solicited by RFP Nos. 94-97. (Novartis Sixth RFP, Nos. 94-97).

[11] This information is solicited by Interrogatory No. 9. (Novartis Pharmaceuticals Corporation's First Set of Interrogatories ("Novartis Interrogatories"), attached as Exh. LL

(Novartis Memo. at 16-17 (internal citations omitted)). Novartis seeks similar documents regarding Exjade and iron chelation therapy from the Litigating States.[12] (Novartis Memo. at 17).

The Government and the Litigating States object on the bases of relevance, overbreadth, and burden. In addition, the Litigating States contend that they are only obligated to produce documents from the agencies that run each state's Medicaid program (these "Single State Agencies" or "SSAs" are mandated by federal law to oversee the states' medical assistance plans, see 42 U.S.C. § 1396a(5); 42 C.F.R. 431.10) and that documents sought from other state entities, including states' public university systems, are not within the SSAs' possession, custody, or control.

C. Legal Standard

Parties are entitled to discovery of documents that are "relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). For purposes of discovery, relevance is interpreted broadly. See, e.g., Nunez v. City of New York, No. 11 Civ. 5845, 2013 WL 2149869, at *2 (S.D.N.Y. May 17, 2013). To be relevant, the requested documents must "appear[] reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). The burden of demonstrating relevance is on the party seeking discovery. Trilegiant Corp. v. Sitel Corp., 272 F.R.D.

---

to First Sheth Decl., No. 9).

[12] These documents are solicited from the Litigating States by RFP Nos. 37, 44, 46 and 51. (E.g., Novartis First RFP to California, Nos. 37, 44, 46; Novartis Second RFP to California, No. 51)

360, 363 (S.D.N.Y. 2010); Mandell v. The Maxon Co., No. 06 Civ. 460, 2007 WL 3022552, at *1 (S.D.N.Y. Oct. 16, 2007). That is, "it is incumbent upon the moving party to provide the necessary connection between the discovery sought and the claims or defenses asserted in the case." 287 Franklin Avenue Residents' Association v. Meisels, No. 11 CV 976, 2012 WL 1899222, at *4 (E.D.N.Y. May 24, 2012). Relevant documents must be produced only if they are within the "possession, custody, or control" of the party from whom discovery is sought. Fed. R. Civ. P. 34(a)(1). "[D]ocuments are considered to be under a party's control when that party has the right, authority, or practical ability to obtain the documents from a non-party to the action." Bank of New York v. Meridien BIAO Bank Tanzania Ltd., 171 F.R.D. 135, 146 (S.D.N.Y. 1997). The demanding party has "the burden of establishing control over the documents being sought." New York ex rel. Boardman v. National Railroad Passenger Corp., 233 F.R.D. 259, 268 (N.D.N.Y. 2006) (citing DeSmeth v. Samsung America, Inc., No. 92 Civ. 3710, 1998 WL 72497, at *9 (S.D.N.Y. Feb. 20, 1998).

"Once relevance has been shown, it is up to the responding party to justify curtailing discovery." Fireman's Fund Insurance Co. v. Great American Insurance Co. of New York, 284 F.R.D. 132, 135 (S.D.N.Y. 2012) (internal quotation marks omitted). Discovery may be curtailed where "the burden or expense of the proposed discovery outweighs its likely benefit," Fed. R. Civ. P. 26(b)(2)(C)(iii), among other reasons. Parties opposing discovery on the basis of burden "must supply specific evidence demonstrating

the nature of the burden." Blagman v. Apple, Inc., No. 12 Civ. 5453, 2014 WL 1285496, at *8 (S.D.N.Y. March 31, 2014); see also Nunez, 2013 WL 2149869, at *3.

D. Relevance[13]

Novartis makes two arguments that the adherence-related documents are relevant. First, it asserts that these documents "are relevant to the appropriateness of the adherence programs at issue here," because "[i]f the Government's own programs encourage patients to adhere diligently to their iron chelation therapies rather than take their medication only on an 'as needed' basis, that is relevant to the . . . argument that BioScrip's patient outreach was improper for doing the same thing." (Novartis Memo. at 11). Novartis points out that the Government's complaints "prominently feature allegations that BioScrip's outreach efforts to Exjade patients were inappropriately conducted and that the information about Myfortic's clinical benefits and importance of adherence to Exjade patients . . . was pretextual."[14] (Novartis Pharmaceuticals Corporation's Reply Memorandum in Further Support of its Motion to Compel Discovery Responses from the United States and the States of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington and Wisconsin ("Reply") at 2; Second Amended Complaint-in-Intervention of the

[13] Although this section focuses on discovery propounded to the Government, it is equally applicable to the Litigating States.

[14] The other operative complaints feature similar allegations with regard to Exjade. (California Compl., ¶¶ 4-7, 70-75, 85-88, 90-107; Multistate Compl., ¶¶ 1, 4-6; Washington Compl., ¶¶ 4-7).

United States ("Government Compl."), ¶¶ 4-5, 8, 140-50, 158, 223-29, 274-76, 279-96). The requested documents will purportedly show

> three important characteristics of what the [G]overnment thinks is an appropriate adherence program. The first is the scope of appropriate communications with the patient. The second is what does the [G]overnment think about the qualifications and training of the personnel who are employed to administer the adherence program, and the third, what are appropriate incentives that should be given to entities or personnel who are administering adherence programs, including what is the appropriate metric for measuring adherence.

(Transcript of Oral Argument dated Nov. 4, 2014 ("Tr.") at 7-8). Second, Novartis argues that "[i]f [Novartis'] allegedly illegal adherence programs resemble those the Government sponsors or otherwise sanctions, it would be compelling evidence that [Novartis'] conduct was reasonable and cannot be a knowing and willful violation" of the Anti-Kickback Statute and the False Claims Act. (Novartis Memo. at 11).

Similarly, Novartis asserts that the requested information concerning treatment protocols for kidney transplant and iron chelation therapy is "plainly relevant to the Government's claims that specialty pharmacies were improperly suggesting that transplant physicians 'switch' patients to Myfortic, or improperly convincing patients to resume Exjade therapies for financial, non-clinical reasons." (Novartis Memo. at 17). The defendant contends that, without information about "the extent to which the Government itself -- through federal and State hospitals and agencies -- endorses Exjade adherence and Myfortic based on clinical reasons, or approved BioScrip as a qualified Exjade provider," its defense will be inappropriately hampered. (Novartis Memo. at 20).

In response, the Government argues that Novartis has not adequately explained the relevance of the information sought, noting that "[t]here is no 'similar government conduct' exception" to the Anti-Kickback Statute (which, in any case, does not apply to the Government), and that there has been no showing that any federal program is similar to the adherence-related initiatives at issue here. (Government Memo. at 12-13). The Litigating States make a similar argument that there is neither a "government conduct" defense nor a "consistent with industry standard" exception to the Anti-Kickback Statute. (Litigating States' Memorandum of Law in Opposition to Novartis' Motion to Compel Further Discovery Responses ("Litigating States Memo.") at 10-11). In addition, the participating plaintiffs point out that, under the False Claims Act and the Anti-Kickback Statute, the plaintiffs must prove that Novartis' violations were "knowing[]" or "knowing[] and willful[]." (Government Memo. at 14-15; Litigating States Memo. at 10); see also 31 U.S.C. § 3729(a)(1); 42 U.S.C. § 1320a-7b(b)(1). This, they contend, depends on "what Novartis knew at the time it engaged in the Exjade scheme and what steps Novartis took at that time to investigate any 'red flag' raised by this scheme." (Government Memo. at 15). As Novartis has admitted that its "defense is not that it modeled its adherence programs on the U.S. programs," the argument goes, information about the Government's programs is irrelevant. (Government Memo. at 14-15).

A primary problem with Novartis' theory -- that what government agencies think is reasonable advice, training,

inducement, and treatment is relevant to an Anti-Kickback Statute or False Claims Act claim or defense -- is that it misapprehends the conduct at issue.[15] For example, Novartis insists that the requested information is "relevant to issues of intent," and points to United States v. Jain, 93 F.3d 436 (8th Cir. 1996), for the proposition that "[e]vidence that the Government itself viewed adherence initiatives as appropriate, and the scope of such sanctioned initiatives[,] makes it more likely than not that [Novartis] did not know that its conduct was wrongful," which would undermine the argument that Novartis' conduct was "willful" as required by the Anti-Kickback Statute. (Reply at 5 & n.7). In Jain, a psychologist was convicted of violating the Anti-Kickback Statute by receiving money for referring patients to an acute-care psychiatric hospital. 93 F.3d at 438. The prosecution conceded that each referred patient was properly hospitalized, and presented no evidence that "any patient received unnecessary care or excessive hospitalization." Id. at 439. Indeed, government witnesses testified that the defendant made patients' well-being his highest priority. Id. On appeal, Dr. Jain challenged the trial court's jury instruction defining willfulness as used in the Anti-Kickback Statute, arguing that the term "means the voluntary, intentional violation of a known legal duty." Jain, 93 F.3d at 440 (internal quotation marks omitted). The court upheld the district court's less rigorous instruction that an act is willful when it is

[15] Given the allegations in the complaints, this misapprehension is understandable, but it is a misapprehension nonetheless.

performed "unjustifiably and wrongfully [and is] known to be such by the defendant." Id. But, notwithstanding the dispute over the willfulness instruction, Jain makes clear (as does the statute) that the conduct prohibited -- and therefore the conduct that must be knowing and willful, however those terms are defined -- is receiving (or offering or soliciting or paying) kickbacks. Jain, 93 F.3d at 439 n.1 (citing 42 U.S.C. § 1320a-7b(b)). Dr. Jain was convicted even though the prosecution admitted that the referrals for which he was paid were appropriate and clinically indicated. See, e.g., United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) ("[T]he giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal . . . . [S]uch kickbacks are more clearly malum in se, rather than malum prohibitum."). Here, then, the question of whether the underlying clinical advice (urging medication adherence for patients who had taken Exjade or recommending Myfortic over similar medications for transplant patients) was appropriate or sound or was similar to advice provided by the Government is simply irrelevant to liability under the Anti-Kickback Statute. See United States v. Nachamie, 101 F. Supp. 2d 134, 154-55 (S.D.N.Y. 2000) ("[A] person violates [the Anti-Kickback Statute] even if he receives a kickback payment for a medically necessary procedure."). The Government admitted at oral argument that the allegations concerning whether pharmacists' and physicians' clinical independence was overborne so that their recommendations were not medically appropriate are not necessary to a cause of action under

the Anti-Kickback Statute. (Tr. at 36-37, 41). Similarly, that information is not material to liability under the relevant sections of the False Claims Act, which focus on whether the defendant knew that a claim for payment was false or fraudulent, whether the defendant knew that a statement material to such a claim was false, and whether there was a conspiracy to violate the statute. Novartis IV, __ F. Supp. 2d at __, 2014 WL 4230386, at *3, *7.

Nor is this information relevant to causation. Judge McMahon has already rejected the notion that the Government or the Litigating States must show that "a pharmacy convinced a physician (in the case of Myfortic) to prescribe a drug that he would not have otherwise prescribed, or convinced a patient (in the case of Exjade) to order a refill that he would not have otherwise ordered." Novartis IV, __ F. Supp. 2d at __, 2014 WL 4230386, at *7-10 (discussing Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001), and 2010 amendment to Anti-Kickback Statute). Instead, under Second Circuit precedent, "it is [] enough that a pharmacy received kickbacks for promoting a particular drug . . . and then submitted claims for reimbursement for that drug after falsely certifying that it was in compliance" with the Anti-Kickback Statute. Id. at *7. Thus, for example, it is irrelevant that, because of widely-held views on medication adherence, a pharmacy would have recommended that a patient refill her Exjade prescription even in the absence of a kickback.

At oral argument (and, to a lesser extent, in its Reply)

Novartis contends that the requested discovery will help determine what constitutes a "recommendation" and an "inducement" under the statute. (Tr. at 9-10; Reply at 4). This argument fails for a number of reasons.

The Government's views of what constitutes a "recommendation" or an "inducement" under the Anti-Kickback Statute are irrelevant to the legal question of the meaning of the statute. No one has argued here that the Department of Health and Human Services or other federal agency has interpreted ambiguous statutory or regulatory terms, which would presumably be entitled to deference under Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) (concerning deference to interpretation of ambiguous statute by agency charged with implementing it), or Auer v. Robbins, 519 U.S. 452 (1997) (concerning deference to interpretation of ambiguous regulation by promulgating agency). See 42 C.F.R. § 1001.952. Rather, the interpretation of these terms is a question of law for the Court, and the Government's opinion on the issue carries no more weight than that of any other litigant.

Novartis does cite a 1994 Special Fraud Alert from the Office of the Inspector General of the Department of Health and Human Services, giving guidance to healthcare providers. Office of the Inspector General, Special Fraud Alert, 59 Fed. Reg. 65,372 (Dec. 19, 1994) ("1994 Fraud Alert"). Novartis contends that "one of the factors that's considered in [the 1994 Fraud Alert] is whether or not the communication was genuine patient counselling or education

or was it more akin to what they call, quote unquote, sales-oriented patient counselling and education." (Tr. at 9). This invents a distinction between "sales-oriented" patient counseling and "genuine" patient counseling that does not exist in the Anti-Kickback Statute or in its regulations -- even those regulations excepting certain conduct from liability. See 42 U.S.C. § 1320a-7b(b)(3) (excluding certain conduct from coverage under statute); 42 C.F.R. § 1001.952 (excluding certain "payment practices" from being "treated as a criminal offense" under the Anti-Kickback Statute). Indeed, the 1994 Fraud Alert makes clear that there is no such distinction; rather, anything of value provided to a person "in a position to generate business for the paying party" that is "[r]elated to the volume of the business generated" may be considered improper under the statute. 1994 Fraud Alert, 59 Fed. Reg. 65,373. Thus, the alert notes that benefits to pharmacies are suspect even if they are "'educational' or 'counseling' contacts" related to the volume of business.[16] 1994 Fraud Alert, 59 Fed. Reg. 65,373. That is, even "genuine" patient counseling that might affect the volume of business generated violates the statute if anything of value is provided in exchange for the counseling. Moreover, the fact that the Government has excluded adherence-related communications from the definition of "marketing

[16] I do not interpret Judge McMahon's quotation of the 1994 Fraud Alert in her discussion of causation in Novartis I as endorsing the distinction urged here. See Novartis I, __ F. Supp. 2d at __, 2014 WL 2324465, at *19-20. Instead, it merely shows that the complaint at issue alleges that Novartis engaged in conduct described in the alert and such conduct indisputedly implicates the Anti-Kickback Statute. Id.

communications" in connection with another statute (the Health Insurance Portability and Accountability Act) (Tr. at 13) is not probative on the question of what conduct violates the Anti-Kickback Statute.

Similarly, Novartis contends that "the legal question" under the Anti-Kickback Statute is whether a payment or gift is "an improper inducement or [] a proper incentive." (Tr. at 10). Again, this is a distinction not found in the statute or the regulations. See, e.g., United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045, 1050 (N.D. Ill. 2002) (noting that, outside the employee context, which is explicitly exempted from coverage, "any compensation could be considered an inducement"). To be sure, the statute and regulations except certain discounts from the definition of "remuneration" under the statute, see 42 U.S.C. § 1320a-7b(b)(3)(A) (excluding discounts that are "properly disclosed" from conduct violative of Anti-Kickback Statute); 42 C.F.R. § 1001.952(h) (excluding certain discounts, including properly-disclosed discounts, from definition of "remuneration" in Anti-Kickback Statute); however, Novartis has not argued in this motion that any of those exceptions apply. (Tr. at 6-7).

Additionally, the Government's own adherence initiatives or treatment protocols cannot be relevant to Novartis' liability under the Anti-Kickback Statute because the Government is fundamentally different from a pharmaceutical company like the defendant. Even if Government-sponsored programs "provide[] financial incentives to

Medicare Part D sponsors in the form of quality bonus payments that are based . . . [in part on] the adherence rate among patients," as Novartis alleges (Tr. at 5), those programs cannot violate the Anti-Kickback Statute because the Government is exempt from its coverage. But even if it were not, the Government is not providing value to a person or entity that is "in a position to generate business" for it. 1994 Fraud Alert, 59 Fed. Reg. 65,373. Thus, its own initiatives shed no light on the appropriateness or legality of the schemes at issue here.

That would end the inquiry if the complaints alleged only violations of the False Claims Act via the Anti-Kickback Statute. Instead, however, each of the plaintiffs involved here also alleges common law claims, including unjust enrichment.[17] (Government Compl., ¶¶ 327-330, 346-349; Multistate Compl., ¶¶ 169-171 (Georgia), 191-193 (Illinois), 220-222 (Indiana), 252-258 (Maryland), 276-279 (Michigan), 303-305 (New Jersey), 327-329 (New York), 353-355 (Oklahoma), 366-371 (Wisconsin); California Compl., ¶¶ 140-142; Washington Compl., ¶¶ 84-89). "The doctrine of 'unjust enrichment' stands for the general principle that 'one person should not be permitted unjustly to enrich himself at the expense of another, but should be required to make restitution of or for

[17] Some plaintiffs include other common law causes of action, including fraud (Multistate Compl., ¶¶ 238-251 (Maryland), 273-275 (Michigan), 299-302 (New Jersey), 346-349 (Oklahoma); Washington Compl., ¶¶ 79-83), conversion (Multistate Compl., ¶¶ 295-298 (New Jersey)), money had and received (Washington Compl., ¶¶ 90-92), tortious interference with business expectation (Washington Compl., ¶¶ 93-100), and payment by mistake of fact (Government Compl., ¶¶ 350-352). I do not find that the requested discovery would be relevant either to those claims or to any defense to them.

property or benefits received, retained or appropriated, where it is just and equitable that such restitution be made.'" Bridgestone/Firestone, Inc. v. Recovery Credit Services, Inc., No. 93 Civ. 168, 1997 WL 225813, at *6 (S.D.N.Y. May 5, 1997) (quoting Black's Law Dictionary 1377 (5th ed. 1979)); see also Northern Shipping Funds I, LLC v. Icon Capital Corp., No. 12 Civ. 3584, 2014 WL 4460423, at *9 (S.D.N.Y. Sept. 5, 2014). "A conclusion that one has been unjustly enriched is essentially a legal inference drawn from the circumstances surrounding the transfer of property and the relationship of the parties." Brand v. Brand, 811 F.2d 74, 81 (2d Cir. 1987) (internal quotation marks omitted). "Equity is the essential component with which a court must concern itself." Counihan v. Allstate Insurance Co., 194 F.3d 357, 361 (2d Cir. 1999).

This cause of action, then, is not narrowly centered on false claims and remuneration for recommendations and referrals, but instead examines the overall fairness of a transaction. This widened focus expands the universe of relevant information. Information showing that, through the schemes at issue, Novartis overrode the clinical judgment of pharmacists or physicians would be relevant to the question of whether it would be inequitable to allow Novartis to retain the fruits of those schemes. Conversely, information "relevant to discovering whether BioScrip's adherence initiative was meaningfully different from the [] initiatives the Government itself promotes" or documents that would reveal whether the Government credited the clinical recommendations that the

specialty pharmacies provided to physicians and patients (Reply at 4) could aid Novartis in arguing that restitution need not be made, particularly if the plaintiffs' False Claims Act causes of action fail.[18] This is true even if, as the Government asserted at oral argument, it bases its theory of unjust enrichment on Novartis' violations of the Anti-Kickback Statute. (Tr. at 34-35). As noted above, the unjust enrichment cause of action is broadly concerned with the equities of the situation. As long as the unjust enrichment claims remain in the case, then, the requested discovery is relevant.

E. Overbreadth

The Government claims that Novartis' requests are overbroad, "purport[ing] to require a wide range of federal agencies and healthcare facilities to devote substantial time, personnel, and other resources to conduct searches based on nebulous concepts," such as "Treatment Protocol[s] for kidney transplants performed at any hospital operated by the United States" and documents relating to policies and initiatives of the Department of Health and Human

[18] The Litigating States complain that Novartis fails to argue in its opening brief "that its adherence requests are relevant to the . . . unjust enrichment claims." (Litigating States Memo. at 11 n.5). To be sure, the Anti-Kickback Statute and False Claims Act receive significant discussion in Novartis' briefs. However, Novartis has, at least in part, based its relevance arguments on the fact that the Government and the Litigating States have chosen to include allegations that the schemes at issue overcame the clinical judgment of pharmacists and physicians and wrongfully induced patients to purchase Exjade or Myfortic. (Reply at 1-2). To the extent that these allegations are relevant to one or more of the claims in this litigation, it is immaterial whether Novartis has identified specific causes of action to which they relate.

Services "relat[ing] to adherence."[19] (Government Memo. at 19; Novartis Second RFP at 10; Novartis Fourth RFP at 24). At oral argument, Novartis limited its requests somewhat, explaining that it seeks documents only from agencies with "health policy making jurisdiction with regard to adherence programs" relating "generally to the concept of why medication adherence is a good thing and what are the scope and parameters of those programs." (Tr. at 12-13, 24). As to the treatment protocols, Novartis seeks "guidance document[s]" that hospitals supply to healthcare providers describing how to "treat kidney transplant patients with immunosuppressive agents." (Tr. at 19).

The parties have not fully explored ways to limit the material at issue in these requests. Because attempts to confer "hit a roadblock . . . on the topic of relevance," the parties have made little progress on limiting the breadth of the document requests. (Tr. at 20-21). Now that the relevance issue is decided, the Government and Novartis shall meet and confer regarding limitations to these requests.[20]

---

[19] The Litigating States make similar arguments with regard to the requests directed at them. (Litigating States Memo. at 11-12). Because in the section below I limit Novartis' requests to documents from the Single State Agencies, I do not address the Litigating States' arguments in detail here.

[20] The Government's burden argument (which is entwined with its overbreadth argument) is wholly unsupported in its papers. At oral argument it offered only that "[t]here are 151 medical centers that are operated by the VA across the country, and . . . approximately 830 outpatient clinics." (Tr. at 46). I encourage the Government to include in these negotiations sufficient support for any claim of burden it chooses to make.

F. Custody and Control

The Litigating States have resisted Novartis' discovery requests, contending that each state is obligated to produce only documents within the possession, custody, or control of its Single State Agency, as it is each state's Medicaid program that has suffered damages as a result of Novartis' alleged conduct. (Litigating States Memo. at 13-16). They maintain that many of the documents sought are not under the control of the states' Attorneys General, including documents from hospital systems associated with the public university systems of California, Illinois, Indiana, Maryland, Michigan, New Jersey, Oklahoma, and Washington, which "are not even part of the executive branch of state government." (Litigating States Memo. at 16-21). Additionally, they argue that the SSAs do not have control over documents of Medicaid providers in their states because they "do not have the authority to get documents from Medicaid providers to respond to requests from private litigants."[21] (Litigating States Memo. at 22).

Novartis claims that, as the states themselves are the plaintiffs and control the litigation, each state has possession, custody, or control of the documents from all of that state's agencies. (Novartis Memo. at 13-14; Reply at 8-9). It adds that, even if the SSAs are the only agencies that need respond to the discovery requests, those agencies have control over documents from other state agencies and entities (including the hospital systems

[21] The Government does not make a similar argument regarding control of information from federal agencies, relying only on its claims of overbreadth and burden.

of the public university systems, to the extent that those are not private corporations (Tr. at 63)) because "as a condition to receiving federal funding for Medicaid, each of the SSAs must have 'control' over third parties with whom they contract and sub-contract to provide Medicaid services." (Reply at 9-10; Novartis Memo. at 14-16). Thus, Novartis disputes the position of the Litigating States' that the SSAs have limited authority over Medicaid providers.

Boardman is instructive here. In that case, the State of New York sued Amtrak alleging breach of a contract to "remanufacture and modernize seven trainsets" owned by Amtrak.[22] 233 F.R.D. at 261. During discovery, Amtrak sought production of documents pursuant to Rule 34, which governs party discovery, from the Office of the State Comptroller. Id. at 262. The court noted "a presumption that separate governmental agencies under state law will not be aggregated together, without a showing of much more." Id. at 262, 264. Because the Department of Transportation and the

[22] Novartis' assertion that the Boardman action "was brought by a specific agency, not the state itself" (Reply at 9 n.11; Tr. at 61), is incorrect. See Boardman, 233 F.R.D. at 262 ("Amtrak notes that the caption in the Complaint identifies the true Plaintiff as the 'State of New York' . . . ."); (Complaint, ¶ 1, State of New York ex rel. Boardman v. National Railroad Passenger Corp., No. 04 Civ. 0962 (N.D.N.Y. Aug. 13, 2004) (identifying plaintiff as the "State of New York . . ., [] a sovereign State"); Stipulation and Order of Dismissal, State of New York ex rel. Boardman v. National Railroad Passenger Corp., No. 04 Civ. 0962 (N.D.N.Y. Dec. 13, 2007) (identifying plaintiff as the "State of New York")). Rather, in Boardman, like in this case, the action was brought in the state's name. The court found that, nevertheless, the real party in interest was a state agency "functioning within [its] 'zone of interest' and authority." Boardman, 233 F.R.D. at 265. The Litigating States make the same argument here. (Litigating States Memo. at 13-14).

Office of the State Comptroller "are not interrelated agencies," do not have "overlapping goals or missions and do not have the ability to share or control the other agency's agenda, documents or personnel," the Court found that the Department of Transportation was the "true actor" in the litigation and that the Office of the State Comptroller was not a party. Id. at 264-65. It then determined that Amtrak had not shown that the Department of Transportation had control over documents from the Office of the State Comptroller. Id. at 268. Along the way, the court dismissed the view advanced in Compagnie Francaise d'Assurance Pour le Commerce Exterieur v. Phillips Petroleum Co., 105 F.R.D. 16, 35 (S.D.N.Y. 1984), that when a government agency sues, it is obligated to produce discoverable information from all other government agencies. The Boardman Court found this pronouncement "too broad and sweeping," as, taken to its logical conclusion, "any lawsuit brought by the State of New York would subject all twenty-two executive agencies, the legislature, the judiciary, quasi-state agencies, and possibly public authorities to disclosure scrutiny, notwithstanding their relative remoteness to the issue of the case." Boardman, 233 F.R.D. at 266. I agree with Boardman that the mere fact that a state or a state agency sues does not mean that the records of all state agencies may be discovered using Rule 34's tools. Rather, there must be a showing that the agency at issue has control over requested information. Id. at 267 ("[N]either the infrastructure nor the affiliation is a determinative factor as to whether Rule 34 may be extended to other

documents holders who are not parties to the litigation, but it is the indispensable element of control that is conclusive.").

Novartis discounts the applicability of Boardman here, contending that the court in that case "relied very specifically on provisions within the New York Constitution" to determine that the "Department of Transportation did not have access or the practical ability to obtain documents from the Office of the State Comptroller," a showing that is missing here. (Tr. at 61). However, it is the propounder's burden to demonstrate that the target has control over the requested documents. Boardman, 233 F.R.D. at 268. The defendant attempts to make this showing by pointing to regulations granting the Single State Agencies "authority . . . to control the administration of Medicaid." (Novartis Memo. at 15). According to Novartis, "[t]his expansive grant of authority" necessarily means that the SSAs have the ability to provide documents from other state agencies. (Novartis Memo. at 15). More to the point, Novartis notes that the SSAs have the power to audit entities providing services paid for by Medicaid, and must maintain certain records on each applicant and beneficiary (Novartis Memo. at 15), as well as "[s]tatistical, fiscal, and other records necessary for reporting and accountability as required" by the Department of Health and Human Services. 42 C.F.R. §§ 431.17, 447.202. It reasons that, therefore, the SSAs have the power to demand information from "state entities involved in the administration of Medicaid." (Novartis Memo. at 15).

However, the fact that the Single State Agencies can demand certain information from such entities does not mean that they are authorized to demand the particular information sought here. Novartis has failed to provide an explicit connection between the information encompassed by the discovery requests at issue and the information that could be gathered for the purposes of an audit or for the purposes of the SSAs' mandated record-keeping. Moreover, Novartis has failed to identify a connection between the purpose of the SSAs' audit and record-keeping responsibilities and the issues in this litigation. See Securities and Exchange Commission v. Tourre, No. 10 Civ. 3229, 2011 WL 350286, at *3 (S.D.N.Y. Jan. 31, 2011) (examining purpose of agreements between U.S. and German governmental agencies regarding exchange of information to determine whether agreement gave SEC control over documents from German agency in enforcement action). Therefore, Novartis has failed to carry its burden of showing that the SSAs have control over documents and information from other state agencies. See Boardman, 233 F.R.D. at 268.

The Litigating States have offered "to produce documents about Exjade from the state agencies that run [their] Medicaid programs." (Litigating States Memo. at 2). Thus, although discovery will be limited to information from the SSAs, the parties still disagree about the substantive scope of that discovery. Novartis and the Litigating States shall therefore meet and confer to attempt to reach a compromise.

Conclusion

Novartis Pharmaceuticals Corporation's motion to compel further discovery responses (Docket no. 245) is granted in part and denied in part. Novartis and the United States of America shall meet and confer regarding production of the requested information within 14 days of the date of this order. Also within 14 days of the date of this order, Novartis shall meet and confer with the States of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington, and Wisconsin regarding the scope of discovery to be produced from their Single State Agencies. In the alternative, the Government and the Litigating States may elect, within the same time frame, to abandon their unjust enrichment claims, thus rendering the requested discovery irrelevant.

SO ORDERED.

James C. Francis IV

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

Dated: New York, New York
November 24, 2014

Copies transmitted this date to all counsel of record via ECF.